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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,054	10/07/2005	Carl-Heinz Kapitz	KAPITZ ET ALL 1 PCT	2970
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WILLIAM COLLARD COLLARD & ROE, P.C. 1077 NORTHERN BOULEVARD ROSLYN, NY 11576			EXAMINER UNDERDAHL, THANE E	
			ART UNIT	PAPER NUMBER
			1651	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/16/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/526,054

Applicant(s)

KAPITZ ET AL.

Examiner

Thane Underdahl

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/7/2005 and 2/28/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 18-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant case these claims contain trademark names for commercially available proteases.

M.P.E.P. § 2173.05(u) recites, "It is important to recognize that a trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus a trademark or trade name does not identify or describe the goods associated with the trademark or trade name." If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. § 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). In the interest of compact prosecution, any protease found in the trademark product will meet the limitation of the claims.

Also claims 28-39 are rejected as being indefinite since they fail to define by what "weight" they are basing their percentage, be it dry weight or total weight of the liquid solution. Clarification is required. In the interest of compact prosecution, any art reading on a similar concentration "by weight" will be applied to these limitations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18-43, 46 and 47 rejected under 35 U.S.C. 102(e) as being anticipated by Pearl et al. (US 2002/0182184, filed May 21, 2002).

These claims are drawn to a method for inhibiting dust mite feces or mold spores and denaturing the keratin of animal hair or for denaturing plant pollen or plant spores comprising applying to an affected area an active ingredient combination comprising at least one enzyme capable of breaking down polypeptides in the dust mite feces or keratin of animal hair or protein chains of plant pollen or plant spores into oligopeptides, mono peptides, dipeptides or tripeptides or of breaking down the mold spores, to eliminate allergenic effects on humans, wherein the enzymes are selected from the group consisting of auxillase, alcalase, bromelain, alphachymotrypsin, collagenase, pepsin, pronase, pancreatin, thrombin and trypsin.

Pearl et al. teach the use of proteases such as alcalase (paragraph 24) to break down dust mite feces, molds and pollens (paragraph 5 and 6) into smaller peptides.

Proteases such as alcalase will inherently break down protein chains into oligopeptides, mono peptides, dipeptides or tripeptides.

The method of Pearl et al. teach a composition that further comprises water 80-99% water (page 7, claim 24). Their method also teach a composition of anionic surfactants at 0.1 to 5% of the composition (paragraph 32), fragrances at a concentration of 0.5% to 2% of the composition, preservatives such as ethyl alcohol at a concentration of 0.5% to 2% and an active ingredient that can comprise one or more enzymes in a concentration of 0.01 to 10% of the composition. The method places the above composition in a container and applies it by spraying (page 7, claim 27). The composition is applied to textiles (paragraph 29). The composition used by their method is in a liquid form (Example 3 and Example 4).

Therefore the reference anticipates claims 18-43, 46 and 47.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-43, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tvedten (WO 98/30236) and Weisberger et al. (WO 99/48918) as supported by Pearl et al. (Cited above) and with further support from Ash et al. (Handbook of Preservatives).

The summary of claims 18-43, 46 and 47 are in the rejection above. This rejection with Tvedten and Weisberger et al. adds two additional claims 44 and 45 which are drawn to a nasal spray. The last lines of the claims "by means of which the active ingredient combination is sprayed directly onto the nasal mucous membranes" is a functional limitation and "A functional limitation must be evaluated and considered...for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used" (M.P.E.P. § 2173.05 (g)). So the claim reads on a nasal spray for application to mucus membranes as opposed to an alternative pathway for the medicine to arrive in the stomach or other destination in the body.

Tvedten teaches "Methods for exterminating pests using compositions comprising at least one protease enzyme. A detergent component may also be utilized in such compositions" (see Abstract). By pests he includes molds (page 5, lines 1-5) and infestations that cause allergic reactions from mites, dander, fur, and hair. While he specifically does not state mite feces, it would be obvious to one of ordinary skill in the art that using a protease will degrade mite excrement as supported by Pearl et al. above. Also Tvedten does not specifically state the enzymes listed in claims 18 or 19 but does mention that the "Protease enzymes may be obtained from various commercial sources" (page 3, line 23). Many of the enzymes listed in claims 18 and 19 are commercial protease solutions. However Weisberger et al. teach the use of, for example, ALCALASE (NOVO Industries) (page 7, lines 1-10). It would be obvious to use the enzymes listed in claims 18 and 19 in the invention of Tvedten. One of ordinary skill in the art would recognize that proteases such as ALCALASE

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will obviously break down protein chains into oligopeptides, mono peptides, dipeptides or tripeptides. The motivation is provided by Tvedten who teaches that his proteases can be obtained from commercial sources and the reasonable expectation of success is provided by Weisberger et al. who successfully uses these commercial proteases towards a similar goal of cleaning composition using protease enzymes (Weisberger et al. See abstract).

Tvedten et al. continues to teach that the liquid composition used in his method comprises water in a range of 60-99.5% (Tvedten page 9, lines 5-10). Also 75% of the weight dry weight of the composition is a surfactant of which as little as 25% of that is an anionic surfactants (page 5, lines 1-25). If 25% of the 75% total surfactants were anionic that means that 18.75% of the total dry weight of the surfactant content. When this number is placed in the entirety of the liquid composition less than 15% of the solution comprises anionic surfactants which meets the limitations of claims 34, 35, 46 and 47.

Furthermore While the art above teaches the components of the composition of claims 34 and 35 M.P.E.P. § 2144.05 II states:

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

Absent any teaching of criticality by the applicant concerning the amounts listed in claims 34 and 35 it would be *prima facie* obvious that one of ordinary skill in the art would recognize that the amounts of anionic surfactant are result effective variables whose ratio and concentration are a matter of routine optimization.

Tvedten also teach the limitations of claims 24, 25, 36, and 37 by adding fragrant oils and extracts at about 0.1 to 5% dry weight of the composition. Once water is added to the composition these values will meet the limitations of claims 24, 25, 36 and 37. Also as mentioned above concerning M.P.E.P. § 2144.05, absent any teaching of criticality by the applicant concerning the amount of fragrance listed in claims 36 and 37 it would be *prima facie* obvious that one of ordinary skill in the art would recognize that the concentration of fragrances are result effective variables whose ratio and concentration are a matter of routine optimization.

Tvedten also teach that their composition may use more than one combination of protease enzymes (page 3, lines 10-15) in a solo or combined concentration of 0.3 to 10% by weight of the composition (page 3, lines 25-30). This meets the limitations of 26-31.

Claim 38 and 39 limit the compositions of claim 18 and 19 respectively by requiring preservatives at a concentration of 0.5 –3% by weight. Tvedten teach the addition of aluminum compounds such as $\text{Al}(\text{OH})_3$ (as supported by Ash et al.) which are known preservatives in a concentration of 0.5% (page 7, lines 19-34)

Claims 40 and 41 apply the composition of claims 18 and 19 by spraying or squirting. Tvedten teaches many methods of application of his composition including spraying (page 8, lines 10-15)

Claims 42 and 43 apply the compositions of claims 18 and 19 to textiles. This too is taught in example 1 of Tvedten who launders clothing with his composition.

In review it would have been obvious to someone skilled in the art to combine the inventions of Tvedten and Weisberger et al. since both share common goals and motivation to use proteases as cleaning solutions for allergy care. The motivation and reasonable expectation of success is provided by Tvedten who shows that proteases can alleviate allergic reactions.

Therefore the references listed above renders obvious claims 29 and 30. claims 18-43, 46 and 47

Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tvedten (WO 98/30236) and Weisberger et al. (WO 99/48918) as applied to claims 18-43, 46 and 47 above, and further in view of and Rennie et al. (U.S. Patent # 4,466,973, 1984).

Claims 44 and 45 apply the compositions of claims 18 and 19 to a nasal spray to the mucous membranes. This is not taught by Tvedten, however Weisberger et al. teaches the use of these proteases as both personal care compositions and cleaning compositions. Weisberger et al. teach several formulations for the protease compositions including mouth sprays and lozenges. Since the invention of Tvedten is to combat allergies it would be obvious to one of ordinary skill in the art to use the formulations of Weisberger et al. since lozenges are known medicaments for allergy treatment. Furthermore both lozenges and nasal sprays are common formulations known to one of ordinary skill in the art to treat allergies as supported by (col 1, lines 25-30). It would therefore have been obvious for the person of ordinary skill in the art to use

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the formulations of Weisberger to treat allergies with a nasal spray. The motivation is provided by Weisberger et al. and Rennie and the reasonable expectation of success to treat allergies is provided by Tvedten.

Therefore the references listed above renders obvious claims 44 and 45.

In summary no claims, as written, are allowed for this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

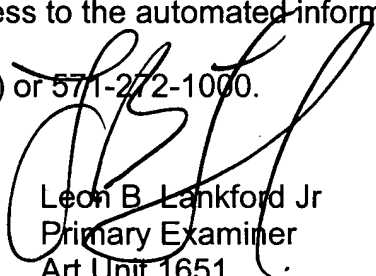
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached during regular business hours, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651



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